



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/660,160	02/21/91	SMITH	148-120CIP3-

JOSEPH E. MUETH
333 SO. GRAND AVE., 37TH FLOOR
LOS ANGELES, CA 90071-1599

EXAMINER	
CHAMBERS, S	
ART UNIT	PAPER NUMBER
1807	29

DATE MAILED:

11/23/92

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on July 10/92 Sept 16/92 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474 | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 15-22 & 36-38 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1-14, 23-35, 39-44 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 15-22 & 36-38 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable;
☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 180 Art Unit 1807. Examiner notes that applicants' preliminary amendment crossed in the mail, having been mailed on the same date as examiners'. The amendment indicates that the subject matter of claims 31-35 and 39-44 are found in the continuation patent application, Serial No. 07/898,019. This application is still being processed at the Patent and Trademark Office; however, in light of applicants' admission that they are the subject of 07/898,019, the obviousness type double patenting rejection found infra has been applied. Regarding applicants' request to correct inventorship, examiner notes that the new oath provided and signed by all of the inventors does not list any continuing data. This oath is intended to supplant the original oath which did list the continuing data. Examiner presumes that this was simply an oversight and has not applied any intervening references. Applicants should provide a new oath containing this continuing data if benefit is indeed desired. In addition, in order to correct inventorship:

For those situations where the error in inventorship included the execution of an oath or declaration under 37 CFR 1.63 naming an improper inventive entity [,] the verified statements by the original named inventors who had so executed the oath or declaration *must explain whether they had reviewed and understood the contents of the specification including the claims as amended by any amendment (as set forth in 37 CFR 1.63) and whether they had reviewed the oath or declaration prior to its execution and if so how the error had occurred in view of such reviews* (emphasis by examiner) See MPEP 201.03. Since this was omitted, applicants' petition must be denied.

Examiner withdraws his rejections under 35 USC 112 first paragraph in light of applicants' arguments regarding sequencing using less than four different chromophores and in light of applicants' amendments regarding sequencing of nucleic acid other than DNA.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that

the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

species

Claims 15-22 and 36-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending application serial no. 07/898,019. Although the conflicting claims are not identical, they are not patentably distinct from each other because attaching the chromophore to the primer would be an obvious method of attaching the chromophore to the nucleic acid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164

USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Claims 36-38 are rejected under 35 U.S.C. 103 as being unpatentable over Kaplan et al. and the admitted prior art methods of Maxim et al. (i.e. Maxim and Gilbert) and Sanger described in the specification (e.g. see page 3) in view of Khanna et al. and Ward et al.

Kaplan et al. teach the separation of the samples by gel electrophoresis and detection of separated material by ultraviolet transmitted material. See column 3, lines 5-10. The admitted prior art methods of Maxim et al. and Sanger sequence by detecting the location of the separated material by radioactivity. They do not teach identification using fluorescent dye molecules. Khanna et al. disclose that fluorescent dye molecules may be attached to oligonucleotides in order to identify the nucleic acid. See column 21, lines 48-51. It is well known in the art and a matter of common knowledge that radioactive materials have serious limitations and drawbacks associated with their use. This is also taught by Ward et al. See column 1, lines 10-39. One of ordinary skill in the art would have been motivated to use a nonradioactive element to avoid these serious limitations and drawbacks. It would have been obvious to one of ordinary skill in the art to substitute fluorescent oligonucleotide tags in the detection system described by Kaplan et al. and use the tags in the admitted prior art methods. Thus applicants invention would have been prima facie obvious at the time of the invention to one of ordinary skill in the art.

Applicant's arguments filed September 16, 1992 have been fully considered but they are not deemed to be persuasive. Applicants argue that in practice, the reaction mixtures are combined and electrophoresed together; they are detected as they pass out of the bottom of the tube; that it can be automated; and that it is very fast; unfortunately, these limitations are not found in the instant claims. Applicants also suggest that sequencing large segments has been a challenge, it is noted that no size limitations are found in the claimed invention. Applicants freely admit that colored labels and fluorescent labels for DNA are prior art, but applicants argue that they

were the first to incorporate such measures into sequencing. Examiner notes that claim 36 is not directed to sequencing, but only to analysis. In addition, it is noted that applicants' working examples incorporate use of specific lasers as well as detection methods which are not part of the invention as claimed, it is not clear that these other methods do not represent the reason for some lag time in art usage of the method. All that is claimed in the instant invention is putting a chromophore on DNA- well known in the art, detection of the location of the DNA by the chromophore-well known in the art, and analyzing the products of a sequencing reaction using the chromophore. In claim 36 the analysis is analysis of anything from size to degradation to mobility. In claims 37 & 38 the analysis appears to be DNA sequencing. Examiner is not contending that the invention is obvious merely because it is a combination of old elements, examiner is simply contending that where it is well known to put a chromophore onto DNA to determine its location, then it is obvious to determine its location in a sequencing reaction as well -- especially when the prior art had previously used hazardous methods such as radioactivity to determine the location.

No claim is allowed.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

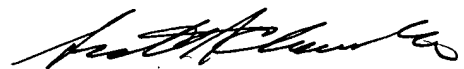
A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY

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Art Unit 1807

PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

An inquiry concerning this communication should be directed to Scott A. Chambers, Ph.D. at telephone number 703-308-3885. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4227. Applicants have cited to In re Wright, 848 F.2d 1216 (Fed. Cir. 1988) to support their position. Examiner notes that Wright is wrong, having been overruled. See In re Dillon, 919 F.2d 688, 693 (Fed. Cir. 1990) (en banc). Shepardizing case law would be appreciated.



Scott A. Chambers
Patent Examiner
Art Unit 1807



MARGARET MOSKOWITZ
SUPERVISORY PATENT EXAMINER
GROUP 180